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Country Information on Maximum Residue Limits Regulations

2004

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Report Highlights:
This report contains country information on the maximum residue limits of pesticides in crops and foods as of June 2004.

Includes PSD Changes: No
Includes Trade Matrix: No
Unscheduled Report
Tokyo [JA1]
[JA]

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Adobe's Japanese language module may need to be installed to view pdf documents from the Japanese government and organizations even if they are in English.

Government agency involved in MRL establishment and its responsibilities

The Ministry of Health, Labor and Welfare (MHLW) maintain a list of maximum residue levels (MRLs) for pesticides. As of June 2004, there were about 9,000 MRLs established for 240 pesticides on about 130 commodities. Each year, MHLW reviews a number of substances for the purposes of establishing MRLs.

Currently, MHLW has a negative list system for pesticide and veterinary drug residues. Crops containing pesticides without MRLs may be distributed in Japan unless they pose a health hazard. To be regarded as such, products without a MRL listed in the present list, residue levels must be safe, usually meaning that the residue levels are below either Codex or the exporting country standards - whichever is stricter. For a full list of MRLs, please refer to (Specifications and Standards for Foods, Food Additives, etc. Under The Food Sanitation Law) the JETRO website: <http://www.jetro.go.jp/se/e/standards_regulation/index.html>.

Laws and regulations guiding the development and enforcement of MRLs for pesticides

There are three major laws pertaining to food safety and standards; the Food Safety Law, Food Sanitation Law and Japan Agricultural Standards Law. The Food Safety Basic Law sets the principles for developing a food safety regime and the role of the Food Safety Commission, a food related risk assessment body (for details, please see JA3029). The Food Sanitation Law ensures the safety and sanitation of foods by MHLW, a food risk management agency. The law prohibits the sale of foods containing poisonous or harmful substances. It also prescribes the standards for foods, additives, food apparatus and container packages, and certain toys. The law is available in English on the Japan External Trade Organization (JETRO) website (http://www.jetro.go.jp/se/e/standards_regulation/index.html).

However, MHLW is in the process of changing the way it controls farm chemicals. In the fall of 2003, the GOJ issued draft list of provisional pesticide maximum residue limits (provisional MRLs). All products sold in Japan, including imports, will have to comply with the current final list or the provisional MRL, beginning in May 2006. Any residues not on the provisional or final lists of chemicals will be illegal after May 2006. MHLW will use the provisional MRLs until establishment of official MRLs based on full risk assessment for individual farm chemicals.

The process for the establishment of MRLs

In establishing MRLs, MHLW obtains the data necessary for pesticides registered for use in Japan through MAFF. For pesticides registered in other countries, MHLW collects data by directly requesting information from the pesticide manufacturers abroad. Data needed for evaluation usually includes data on acute toxicity, subacute toxicity, chronic toxicity, carcinogenicity, reproductive toxicity, teratogenicity, mutagenicity, pharmacokinetic and general pharmacological parameters, animal metabolism, and plant metabolism as well as residue data (for commodities treated with target pesticides).

Update of the MRL information

The JETRO information website (http://www.jetro.go.jp/se/e/standards_regulation/index.html) contains important MRL information and is updated once every year or two, as necessary. There is also a useful website for the list of food additives, residue chemical limits, and specifications for packaging and containers (http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-lists). MHLW has an English website that contains some food safety information (http://www.mhlw.go.jp/english/topics/importedfoods/index.html). The websites are also updated on an as needed basis.

Regulatory process for the establishment of import MRLs

MHLW establishes MRLs on each pesticide mainly based on scientific data and information provided by its manufacturer. The information includes its range and scope of use, such as registered crops and countries. MHLW basically does not discriminate between import MRLs from MRLs registered for domestic use.

After the implementation of the positive list system, for pesticides mainly used abroad, a request for the establishment of MRLs may be made using 'Guideline for Application for Establishment and Revision of Maximum Residue Limits for Agricultural Chemicals used outside Japan' (http://www.mhlw.go.jp/english/topics/foodsafety/dl/importguideline.pdf) with necessary documentation.

Crop groups, individual crops used for the establishment of MRLs

MRLs are established for each major crop and for crops groups for minor crops. Below is a typical example of grouping of crops for MRL establishment.

Rice (brown rice)

Wheat
Barley
Rye
Corn (including Maize, Sweet corn)
Buckwheat
Other cereal grains

Soybeans (dry)
Beans (dry)
Peas
Broad beans
Peanuts (dry)

Other legumes/pulses

Potato
Taro
Sweet potato
Yam
Konjac
Other potatoes

Sugar beet
Sugarcane

Japanese radish (including Radish) (root)
Japanese radish (including Radish) (leaf)
Turnip (including Rutabaga) (root)
Turnip (including Rutabaga) (leaf)
Horseradish
Watercress
Chinese cabbage
Cabbage
Brussels sprouts
Kale
KOMATSUNA
KYONA
Qing-geng-cai
Cauliflower
Broccoli
Other cruciferous vegetables

Burdock
Salsify
Artichoke
Chicory
Endive
SHUNGIKU
Lettuce (Cos lettuce, Leaf lettuce)
Other composite vegetables

Onion
Welsh (including Leek)
Garlic
NIRA
Asparagus
Multiplying onion (including Shallot)
Other liliaceous vegetables

Carrot
Parsnip
Parsley
Celery
MITSUBA
Other umbelliferous vegetables

Tomato

Pimento (Sweet pepper)
Egg plant
Other Solanaceous vegetables

Cucumber (including Gherkin)
Pumpkin (including Squash)
Oriental pickling melon (vegetable)
Water melon
Melons
MAKUWAURI
Other cucurbitaceous vegetables

Spinach
Bamboo shoots
Okra
Ginger
Peas (with pods, immature)
Kidney beans (with pods, immature)
Soybeans

Button mushroom
SHIITAKE
Other mushrooms
Other vegetables
UNSHU orange
NATSUDAIDAI (flesh)
NATSUDAIDAI (peel)
NATSUDAIDAI (whole)
Lemon
Orange (including Navel)
Grapefruit
Lime
Other citrus fruits

Apple
Japanese pear
Pear
Quince
Loquat

Peach
Nectarine
Apricot
Japanese plum (including Prunes)
Mume plum
Cherry

Strawberry
Raspberry
Blackberry
Blueberry
Cranberry
Huckleberry
Other berries

Grape
Japanese persimmon

Banana
Kiwifruit
Papaya
Avocado
Pineapple
Guava
Mango
Passion fruit
Date

Other fruits

Sunflower seeds
Sesame seeds
Safflower seeds
Cotton seeds
Rape seeds
Other oil seeds

Ginkgo nut
Chestnut
Pecan
Almond
Walnut
Other nuts

Tea (Green, Black, Oolong, Wulung tea)
Coffee beans
Cacao beans
Hop

Cattle, muscle
Pig, muscle
Sheep, muscle
Horse, muscle
Deer, muscle
Goat, muscle
Rabbit, muscle
Reindeer, muscle
Other terrestrial mammals, muscle

Cattle, fat
Pig, fat
Sheep, fat
Horse, fat
Deer, fat
Goat, fat
Rabbit, fat
Reindeer, fat
Other terrestrial mammals, fat

Cattle, liver
Pig, liver
Sheep, liver
Horse, liver
Deer, liver
Goat, liver
Rabbit, liver
Reindeer, liver
Other terrestrial mammals, liver
Cattle, kidney
Pig, kidney
Sheep, kidney
Horse, kidney
Deer, kidney
Goat, kidney
Rabbit, kidney
Reindeer, kidney
Other terrestrial mammals, kidney

Cattle, edible offal excluding liver and kidney
Pig, edible offal excluding liver and kidney
Sheep, edible offal excluding liver and kidney
Horse, edible offal excluding liver and kidney
Deer, edible offal excluding liver and kidney
Goat, edible offal excluding liver and kidney
Rabbit, edible offal excluding liver and kidney
Reindeer, edible offal excluding liver and kidney
Other terrestrial mammals, edible offal excluding liver and kidney

Cattle, milk
Sheep , milk
Goat, milk
Other terrestrial mammals, milk

Cattle, milk fat
Sheep, milk fat
Goat, milk fat
Other terrestrial mammals, milk fat

Chicken, muscle
Duck, muscle
Turkey, muscle
Quail, muscle
Goose, muscle
Pheasant, muscle
Chukar partridge, muscle
Other poultry, muscle

Chicken, fat
Duck, fat
Turkey, fat
Quail, fat

Goose, fat
Pheasant, fat
Chukar partridge, fat
Other poultry, fat

Chicken, liver
Duck, liver
Turkey, liver
Quail, liver
Goose, liver
Pheasant, liver
Chukar partridge, liver
Other poultry, liver

Chicken, kidney
Duck, kidney
Turkey, kidney
Quail, kidney
Goose, kidney
Pheasant, kidney
Chukar partridge, kidney
Other poultry, kidney

Chicken, edible offal excluding liver and kidney
Duck, edible offal excluding liver and kidney
Turkey, edible offal excluding liver and kidney
Quail, edible offal excluding liver and kidney
Goose, edible offal excluding liver and kidney
Pheasant, edible offal excluding liver and kidney
Chukar partridge, edible offal excluding liver and kidney
Other poultry, edible offal excluding liver and kidney

Chicken, eggs
Turkey, eggs
Other poultry, eggs

Chicken, egg yolk
Turkey, egg yolk
Other poultry, egg yolk

Catfish
Other freshwater fish
Sweet fish
Carp
Crucian carp
order Clupeiformes(cultivated in freshwater, excluding sweet fish)
order Cypriniformes

Salmon
Salmon, muscle
Salmon, skin
Trout
order Anguilliformes

Other salmonidae
Other diadromou fish

Eel
Marine fish
order Perciformes
Other marine fish
Red Sea Bream

Shrimps or prawns
Lobster
Crayfiish
Other crustaceans

Oyster
Abalone
Other aquatic animals

Other animals

Honey

Surveillance / testing program for pesticide residues in imported foods, number of samples tested, how priorities are identified, availability of test results, sampling and testing procedures

Quarantine offices (for imported crops) and local laboratories in municipalities (for domestic crops) conduct monitoring tests for pesticides for which MRLs are established. The purpose of the monitoring tests is to check whether crops in the marketplace comply with established MRLs. Any product found to contain a substance in excess of an established MRL may not be marketed in Japan.

At ports, MHLW normally monitors between 3-10% of imports for antimicrobials, chemical residues, food additives, microorganisms, fungal toxins and unapproved genetically modified products. The annual monitoring plan announced for fiscal year 2004 includes testing 76,000 samples for antimicrobials, residue chemicals, food additives, microorganisms, fungal toxins and unapproved genetically modified products. Among them 39,600 samples are for testing chemical residues (agricultural chemicals and antimicrobials).

Its sampling is based on Codex recommendations: 299 samples for each food group, enabling it to find violations of below 1% at 95% level of confidence. MHLW may increase the sampling ratio based on past violation and the significance of the violations. In the case of monitoring for imports, MHLW bears the cost of monitoring and laboratory tests.

There are 31 quarantine stations around Japan and six of them have testing facilities. Besides those quarantine stations, there are two imported food testing and inspection centers that have the capability to test. MHLW has designated about 60 testing laboratories to do monitoring tests on behalf of MHLW as of June 2004.

For imported foods, MHLW has three levels of testing and regulating schemes. First is the normal monitoring. When MHLW finds two or more violations or problems with a certain imported food, it imposes testing-by-order. Finally, if MHLW finds the problem persists, it may implement a comprehensive ban of imports from the origin or the persistent problem.

MHLW has been conducting surveys of residues, including pesticides without MRLs, to obtain basic data for the establishment of MRLs. The monitoring test results typically show that less

than 0.1% of the samples tested were above the established MRLs. The monitoring test plans and results are made available to the public on the MHLW Japanese website.

Details of testing programs for imports are summarized in the Gain Report JA4005.

Codex MRLs' role

Under the negative list system currently applied in Japan, there are cases where no MRL is established for a specific pesticide on a specific crop. In those cases, MHLW makes a determination as to whether the residue level potentially influences human health. To make the determination, MHLW at first refers to Codex MRLs. If there are no Codex MRLs, MHLW refers to the MRLs in the producing/exporting country. MHLW will make a decision whether it needs to take an action based on such information.

In preparation for the introduction of the positive list system in 2006, MHLW is in the process of establishing provisional MRLs. To establish provisional MRLs, MHLW's basic position is to adopt Codex standards whenever possible. (Details see Gain Report JA4051)

Actions to be taken when residues are found above the MRL

Crops not meeting the standards and specifications of the Food Sanitation Law, including MRLs, were discarded, re-exported, reconditioned, or otherwise disposed of.

The first step is when monitoring test results reveal a violation, monitoring of the same product from the same country of origin is increased by a factor of 10, usually to 50%. If a second violation is found under the increased monitoring program, testing-by-order is triggered for the food product. Depending on the ability to trace back the product, the testing-by-order may apply to an exporting country, a region, or a specific producer or manufacturer. When a human health-related incident occurs or serious health hazard is strongly suspected from an imported food, one violation under the monitoring program can trigger testing-by-order. If MHLW finds the problem persists, it may implement a comprehensive ban of imports.

Testing-by-order is a mandatory testing program under which each shipment has to be held until the test result shows negative. Tests under testing-by-order are performed at one of the designated domestic laboratories at the expense of the importer.

MHLW lifts the order of testing when it is confirmed that no violated foods are to be exported due to appropriate measures that prevent the same incident from occurring again from the exporting country, region, manufacturer or processor.

The comprehensive ban may be considered by MHLW if "there are a considerable number of violations (over 5% violation ratio for the most recent 60 samples under the testing-by-order for imported foods) or human health hazard occurrence or situations that have a potential of adulterating foods (e.g., radioactive contamination from a nuclear plant accident). The ban will only be imposed after consultation with the exporting country, an investigation of production or manufacturing finds a potential hazard and the relevant expert committee, the Pharmaceutical and Food Sanitation Committee affirms the ban.

Default pesticide enforcement level

Under the current negative list system, there is no default pesticide enforcement level. MHLW is considering 0.01 ppm for the default tolerance after the introduction of the positive list system in 2006 (Details see Gain Report JA4051)

The coordinates of relevant offices and online information

The United States Department of Agriculture, Foreign Agricultural Service provides U.S. exporter assistance and may be able to assist in identifying relevant local contacts for additional information:

Office of Agricultural Affairs
U.S. Embassy, Tokyo
Tel: 81-3-3224-5102
Fax: 81-3-3589-0793
Email: agtokyo@usda.gov

Information on food safety regulations in Japan including those on pesticide residues:

The JETRO information website:
(http://www.jetro.go.jp/se/e/standards_regulation/index.html)
The San Ei Gen website: (http://www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/e-lists).
MHLW' English website that contains some food safety information:
(http://www.mhlw.go.jp/english/topics/importedfoods/index.html)

MHLW responsible division:

Standards and Evaluation Division
Department of Food Safety
Ministry of Health, Labor and Welfare
1-2-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-8916
Japan
Fax: 81-3-3501-4868

Importer association contact point:

Japan Fresh Produce Import and Safety Association (Nisseikyo)
Suehiro Bldg.
1-12-16 Kanda Izumi-cho, Chiyoda-ku, Tokyo 101-0024 Japan.
Tel: 81-3-5833-5141
Fax: 81-3-5833-5140